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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/981,002

10/17/2001

Wayne M. Barnes

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06/03/2008

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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

06/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/981,002	Applicant(s) BARNES, WAYNE M.	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/10/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner of Record

As an initial matter, it is noted that the examiner of record has been changed from Jeffrey Fredman, Art Unit 1637, to Christopher M. Babic, Art Unit 1637.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 6, 2008 has been entered. Claim(s) 17-31 are pending.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The above claim recites the limitation "said *Thermus aquaticus* DNA polymerase" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112 - New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim(s) 17-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the limitation reciting, "wherein the ration of DNA polymerase activity of the first DNA polymerase to the DNA polymerase activity of the second DNA polymerase is from about 100:1 up to about 600:1", added in Applicant's responses dated May 7, 2007 and November 19, 2007, was not contemplated in the disclosure at the time the application was filed, and thus, is new matter.

Applicant points to page 19, lines 26-28 and page 21, lines 10-60 of the disclosure as providing support for this amendment; however, these portions are not considered to explicitly or inherently provide support for the above amendment

because, as understood by the examiner, it appears that Applicant has claimed the reverse of the E1:E2 polymerase ratios contemplated at the time of invention. Applicant recites on pages 20-21 of the specification that:

"I have discovered that the beneficial effects of a 3'-exonuclease can be obtained with an unexpectedly minute presence of one or more DNA polymerases which exhibit 3'-exonuclease activity (herein called "E2") such as certain Archaeobacterial DNA polymerases, whilst efficient extension is being catalyzed by a large amount of one or more DNA polymerases which lack 3'-exonuclease activity, such as KlenTaq-278 or AT (herein called "E1"). ,..., For most applications, the mixture of DNA polymerases must be at a relative DNA polymerase unit ratio of E1 to E2 of at least about 4:1, before enhanced product length and yield can be achieved. When Pfu DNA polymerase was used in the formulation, the ratio preferably is in the range 80 to 1000 parts KlenTaq-278 per part (unit) Pfu, more preferably from about 150 to about 170:1, and most preferably, is about 160:1, depending somewhat on the primer-template combination."

The cited new matter recites that the activity (amount) of the first DNA polymerase, i.e. E2 (Archaeobacterial, exo+), is greater than the activity (amount) of the second DNA polymerase, i.e. E1 (exo-). Thus, the claim appears to contradict what was discovered at the time of invention.

Claim Rejections - 35 USC § 102 - Withdrawn

Applicant's claim amendments and supplemental remarks (remarks section I) regarding the rejection of claim(s) 17-22, 24, 26, 27, 29, and 30 over Sorge are sufficient to overcome the grounds of the rejection. Sorge does not disclose polymerase ratios greater than 9:1. Thus, the rejection has been withdrawn.

Conclusion

Claim(s) 17-31 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Patent Examiner

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